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Preventive Cardiovascular Nurses Association

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December 7, 2005

Andrew von Eschenbach, M.D.
Acting Commissioner
U. S. Food and Drug Administration (HF-1)
RM 1471
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Von Eschenbach:

On behalf of the board of directors of the Preventive Cardiovascular Nurses Association, I submit the following reiteration of our comments regarding the professional labeling of aspirin in the primary prevention of cardiovascular disease presented at the advisory committee meeting December 8, 2003.

The Preventive Cardiovascular Nurses Association (PCNA) is the leading nursing organization dedicated to preventing cardiovascular disease through assessing risk, facilitating lifestyle changes, and guiding individuals to achieve treatment goals. Heart disease and stroke affect over 70 million Americans.¹ Sadly, many do not survive the initial cardiovascular event to become candidates for secondary prevention. In order to change the tide of this epidemic, we must develop and implement safe, efficacious and cost-effective primary interventions. We support the American Heart Association's (AHA) "Guidelines for Primary Prevention of Cardiovascular Diseases and Stroke: 2002 Update."² A key feature of this guideline is the identification of persons who are at a substantial risk for a primary cardiovascular event in the next 10 years. This was defined as a risk of $\geq 10\%$ based on age, gender, and the presence of multiple coronary risk factors. The recommendations for this group include low-dose aspirin.

Eidelman and colleagues published a meta-analysis of 5 large randomized trials of aspirin in the primary prevention of cardiovascular disease (CVD).³ Over 55,000 persons (11,466 of whom were women) were included in this analysis. Aspirin users were found to have a 32% reduction in primary non-fatal myocardial infarction. Their recommendations are in accordance with those of the AHA. A summary of the evidence regarding aspirin for primary prevention by Hayden and colleagues also supports the AHA position.⁴

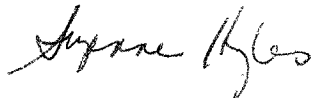
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To summarize, we support the use of low-dose aspirin in the primary prevention of persons at high risk of acute myocardial infarction. This is, of course, with full recognition that there are persons at high CVD risk in whom aspirin (even low dose) may be associated with gastrointestinal bleeding or hemorrhagic stroke. We feel that the net benefit in the group described above has been clearly demonstrated.

The challenge that we face as healthcare professionals is the dissemination of this information to the public and to our colleagues in a way that they fully understand the risks and benefits of this therapy. We would embrace the opportunity to participate in the education other healthcare providers in the measurement of global risk and the potential benefit of aspirin in high risk persons. In addition we will seek opportunities to educate the public about aspirin and to encourage those at risk to seek the advice of their health care providers regarding aspirin use.

Sincerely,



Suzanne Hughes, M.S.N., R.N.
Chair, Advocacy
Preventive Cardiovascular Nurses Association

cc: Charles Ganley, M.D.
Robert Temple, M.D.
Douglas C. Throckmorton, M.D.
Norman L. Stockbridge, M.D., Ph.D.
Document Management Branch

¹ American Heart Association. Heart Disease and Stroke Statistics — 2005 Update. Dallas, Tex.: American Heart Association; 2004.

² Pearson TA, Blair SN, Daniels SR, et al. AHA Guidelines for Primary Prevention of Cardiovascular Disease and Stroke: 2002 Update: Consensus Panel Guide to Comprehensive Risk Reduction for Adult Patients Without Coronary or Other Atherosclerotic Vascular Diseases. American Heart Association Science Advisory and Coordinating Committee. Circulation. 2002 Jul 16;106(3):388-91

³ Eidelman RS, Hebert PR, Weisman SM, Hennekens CH. An update on aspirin in the primary prevention of cardiovascular disease. Arch Intern Med. 2003 Sep 22;163(17):2006-10

⁴ Hayden M, Pignone M, Phillips C, Mulrow C. Aspirin for the primary prevention of cardiovascular events: a summary of the evidence. Ann Intern Med. 2002; 136: 161-172